DCH/LPH-503 (01/05)

Michigan Department of Community Health
Board of Pharmacy
P.O. Box 30670
Lansing, Michigan 48909
(517) 335-0918
www.michigan.gov/healthlicense

PROCEDURE FOR OBTAINING A MANUFACTURER/WHOLESALER LICENSE

Authority: P.A. 368 of 1978, as amended.
This form is for information only.

NOTE: An application accompanied by the appropriate fee is valid for two years. If an applicant fails to complete the requirements for licensure within two years from the date of filing the application, the application is no longer valid.

Enclosed is an application for a manufacturer/wholesaler license, Compliance Checklist, Public Health Code (PA 368 of 1978, as amended) and the Administrative Rules for the Michigan Board of Pharmacy.

Manufacturers or wholesale distributors of any prescription drug doing business in the State of Michigan, whether or not located in the State of Michigan, shall be licensed by the Board of Pharmacy and pay a fee of $85.00. If controlled substances are also to be manufactured or distributed, an additional fee of $85.00 is required under provisions of the Michigan Public Health Code.

A manufacturer or wholesale distributor that distributes prescription drugs in Michigan from a location outside of this state must obtain a license to do business in Michigan. (If the license is for a corporation, the license should be obtained in the name of the parent or subsidiary corporation under which the business will be conducted in Michigan.)

A manufacturer or wholesale distributor that manufactures or distributes prescription drugs in this state from one or more locations in this state shall obtain a separate license for each location in this state from which prescription drugs are manufactured or distributed. A separate application with all supporting documents must be filed for each location.

PROCEDURES FOR OBTAINING A NEW MANUFACTURER/WHOLESALER LICENSE

1. The application must be completed in its entirety and returned to the Board office with the appropriate fee(s).

2. With the application, submit photographs of the interior and exterior premises and a floor plan of the area to be licensed. DO NOT SEND A COPY OF BLUEPRINTS. Applicants who handle controlled substances may submit a copy of their DEA registration in lieu of photographs and floor plan.

3. If you are a manufacturer or distributor of biologicals, submit a copy of the FDA registration for the site to be licensed.

4. Applicants from businesses that are partnerships, corporations, or operating under an assumed name must file the application for a manufacturer/wholesaler license along with copies of:

    1) Partnership Certificates
    2) Articles of Incorporation and/or Assumed Name Certificates

5. Provide a list or catalog of all drug products manufactured or distributed in Michigan.

6. Complete the Compliance Check List in its entirety.

7. Complete the information on the application regarding the opening date, name of person to contact and telephone number.

Upon receipt of #1-7 above, your application will be reviewed for compliance under Administrative Rule 23(a-f) of the Michigan Board of Pharmacy. If a satisfactory inspection and/or review is received, a permanent identification number will be assigned and the license(s) will be issued.

PROCEDURE FOR TRANSFER OF A MANUFACTURER/WHOLESALER LICENSE

The following changes constitute a transfer:

1. Change of ownership.

2. Sale of stock from original owner to new owner.

If you are applying for a transfer of a manufacturer/wholesaler license, you must follow steps 1 through 7 as outlined in Procedures for Obtaining a New Manufacturer/Wholesaler License.

Upon receipt of the completed application, fee(s), and required documentation, an inspection or review will be requested. If a satisfactory inspection or review is received , a new permanent identification number and new license(s) will be issued.

PROCEDURE FOR MISCELLANEOUS CHANGE

The following changes constitute miscellaneous changes. Complete the application in its entirety and return it to the Board office.

1. Partner or stockholder change.

    a. Stockholder change - submit minutes of stockholder meeting reflecting the change in corporate ownership.

    b. Corporation or partnership change - submit amended Articles of Incorporation reflecting the change.

2. Change in name of corporation where no change in ownership occurs.

    a. Submit a letter indicating the effective date of the name change.

    b. Submit a copy of the amended Articles of Incorporation.

    c. If you want the license(s) re-issued under the new name, submit $10.00 for each license held. Re-issuance of the license(s) is not required.

PROCEDURE FOR CHANGE IN LOCATION

A fee is required for an existing manufacturer/wholesaler moving to a new location.

1. Follow steps 1 through 7 as outlined under Procedures for Obtaining a New Manufacturer/Wholesaler License on page 1 of these instructions

2. Complete the information on the application regarding the proposed date of the change of location, person to contact and telephone number.

Upon receipt of the completed application, fee(s), and required documentation, an inspection or review will be requested. If a satisfactory inspection or review is received , the same permanent identification number will be retained and new license(s) will be issued to reflect the new address.

PROCEDURE FOR RELICENSURE

1. The application should be completed in its entirety and returned to the Board office with the appropriate fee(s).

QUARTERLY REPORTING - SCHEDULE 2

The Michigan Public Health Code requires that wholesalers and manufacturers report, on a quarterly basis, all Schedule 2 controlled substances that are sold to licensed practitioners and retail pharmacies. To facilitate compliance with the reporting requirements, you may submit your written reports in whatever format you currently utilize, PROVIDED all the following information for Schedule 2 controlled substances is included:

1. Name, address, and ZIP Code of purchaser;
2. Purchaser's DEA number (7 Digits prefixed by 2 alpha characters);
3. Drugs listed by name (generic, trade or brand name) and NDC number;
4. Date of sale (the date the order is filled by the supplier);
5. Quantity of each drug purchased by dosage unit;
6. Name of the supplier;
7. Address of the supplier; and
8. DEA number of the supplier.

NOTE: The ARCOS format lacks flexibility and cannot be utilized for these reports.

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APPLICATION FOR MANUFACTURER/WHOLESALER LICENSE

Authority: Public Act 368 of 1978, as amended
If this form is not completed, a license will not be issued

A controlled substance license is required for every person who prescribes, manufactures, distributes, or dispenses any controlled substance in Michigan as described in Article 7 of Public Act 368 of 1978, as amended. Information on obtaining a Federal controlled substance license may be obtained by contacting the Regional Branch, Drug Enforcement Administration, 431 Howard Street, Detroit, MI 48226 (Telephone (313) 234 - 4300).

Board Use Only
License Number
Date of Licensure

Type or Print Only

I AM APPLYING FOR THE FOLLOWING LICENSE(S):

(If you manufacture, repackage, relabel, or distribute controlled substances in Michigan, you must also apply for a controlled substance license):

- ☐ New
  - ☐ Manufacturer/Wholesaler Fee: $85.00 71 - 5306 -01
  - ☐ Controlled Substance License Fee: $85.00 CODES?
- ☐ Transfer
  - ☐ Manufacturer/Wholesaler Fee: $85.00
  - ☐ Controlled Substance License Fee: $ 85.00
- ☐ Change of Location
  - ☐ Manufacturer/Wholesaler Reissue Fee: $65.00
  - ☐ Controlled Substance License Fee: $85.00
- ☐ Relicensure
  - ☐ Manufacturer/Wholesaler Fee: $105.00
  - ☐ Controlled Substance License Fee: $85.00
- ☐ Miscellaneous
  - ☐ Partner or Shareholder Change: No fee required.
  - ☐ Name Change Fee: $10.00 for each new license issued (reissuance of license(s) not required).

Type of Operation:
- ☐ Manufacturer
- ☐ Repackager
- ☐ Full Service Wholesaler
- ☐ Buying Group
- ☐ Import/Export
- ☐ Distribution Center
- ☐ Other _____

Your check or money order drawn on a U.S. financial institution and made payable to the **STATE OF MICHIGAN** must accompany this application **DO NOT SEND CASH**. Fees are deposited upon receipt and can only be refunded under refund rules promulgated by the Department.

CURRENT OWNERSHIP INFORMATION

Name of Company (Under Which You Conduct Business)	Current Michigan Permanent I.D. Number
Address of Facility (Street, City, Sate and ZIP Code)	
Mailing Address if Different from Location Above (Street and Number, City, State, and ZIP Code)	
Name of Corporation (if Different Than Name Above)	
Check Type of Ownership: ☐ Individual ☐ Corporation ☐ Partnership	Federal I.D. Number
Name of Current Contact Person	Telephone number
Address (Number and Street, City, State, and ZIP Code	

The Department of Community Health will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need assistance with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency

Name

If PARTNERSHIP OR CORPORATION, include names, addresses, telephone numbers of all partners or shareholders, including the percentage of stock owned by each . Use a separate sheet, if necessary.

Name and Address	Telephone	Amount of Stock Owned	Social Security Number

The individual named below is hereby designated by the applicant to be the license to be licensee for the within named manufacturer or wholesaler distributor or responsible for compliance with federal and state laws and Board of Pharmacy rules regulating the manufacturing and distribution of prescription drugs.

Name _____ Address _____

Check the appropriate answer to each of the following questions. Attach a detailed explanation for any Yes answer you check.

1. Has any director, employee, officer, owner, partner, or stockholder ever been convicted of a misdemeanor or a felony?	❒ Yes ❒ No
2. Has the applicant or any director, employee, officer, owner, partner, or stockholder ever had a financial interest in a pharmacy, manufacturer, or wholesaler distributor which has	
a. been denied a license or federal registration?	❒ Yes ❒ No
b. had its license or federal registration limited, surrendered, suspended, or revoked?	❒ Yes ❒ No
c. been subject to any other criminal, civil, or administrative penalty?	❒ Yes ❒ No
3. Has the applicant or any owner, director, employee, partner, or stockholder ever had a license or federal registration	
a. denied, limited, suspended, or revoked?	❒ Yes ❒ No
b. been subject to any other criminal, civil, or administrative penalty?	❒ Yes ❒ No

CERTIFICATION

I understand that it is the policy of this agency to secure a criminal conviction history as part of their pre-licensure screening process. I authorize this agency to use the information provided in this application to obtain a criminal conviction history file search from the Central Records Division of the Michigan Department of State Police or other law enforcement or judicial record keeping organization.

I further consent to the release of information to this agency regarding any disciplinary investigations conducted by a similar licensure, registration, or specialty certification board of this or any other state, of the United States military, of the federal government, or of another country.

The statements in this application are true and correct. I have not withheld information that might affect the decision to be made on this application. In signing this application, I am aware that a false statement or dishonest answer may be made on this application. In signing this application, I am aware that a false statement or dishonest answer may be grounds for denial of my application or revocation of my license and that such misrepresentation is punishable by law.

Signature of Applicant	Date

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COMPLIANCE CHECK LIST FOR MANUFACTURERS/WHOLERSALERS

Authority: Public Act 368 of 1978, as amended.
If this form is not completed, then a license will not be issued.

Type or Print Only

Name of Manufacturer/Wholesaler		Date Opening, Transferring or Relocating
Street Address		City
State	ZIP Code	County
Name of Contact Person		Telephone Number

If you handle controlled substances, complete the following as applicable, and submit a copy of your DEA registration.

DEA Registration Number	Expiration Date of Registration
Application Date (If recently applied)	

Check the appropriate answer to each of the following questions.

MANUFACTURING PRACTICE	
Do you maintain the building, operate the equipment, and administer the controls, records and methods used for, and in connection with, the manufacturing, processing, packing, labeling, holding, and distributing of all prescription drugs in conformity with current good manufacturing practice pursuant to the criteria set forth in the provisions of 21 C.F.R. 211.1 TO 211.208?	☐ Yes ☐ No
WHOLESALING PRACTICE	
1. Does the facility meet the following standards for the storage and handling of prescription drugs and the establishment and maintenance of prescription drug distribution records:	
a. Is this facility of suitable size to facilitate cleaning, maintenance and proper operations?	☐ Yes ☐ No
b. Does the facility have storage areas that are designed to provide adequate lighting,ventilation, temperature, sanitation, humidity, space, equipment and security conditions?	☐ Yes ☐ No
c. Does the facility have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated or that are in immediate or sealed secondary containers that have been opened?	☐ Yes ☐ No
d. Is this facility maintained in a clean and orderly condition?	☐ Yes ☐ No
e. Is this facility free from infestation by insects, rodents, birds, or vermin of any kind?	☐ Yes ☐ No
2. Does this facility meet the following security and general provisions:	
a. Is access from the outside kept to a minimum and well -controlled?	☐ Yes ☐ No
b. Is the outside perimeter of the facility well-lit?	☐ Yes ☐ No
c. Is entry into areas where prescription drugs are held limited to authorized personnel?	☐ Yes ☐ No

Name

d.	Are all facilities equipped with an alarm system to detect any entry after hours?	☐ Yes ☐ No
e.	Are all facilities equipped with a security system to provide protection against theft and diversion?	☐ Yes ☐ No
f.	Are computers and electronic records kept under security to prevent tampering with the records?	☐ Yes ☐ No
3.	Will all prescription drugs be stored at appropriate temperatures and conditions in accordance with label requirements or in accordance with requirements in the current edition of the official compendium?	☐ Yes ☐ No
4.	Do you maintain and enforce written policies and procedures which include all of the following:	
a.	Making sure the oldest approved stock of a prescription drug product is distributed first?	☐ Yes ☐ No
b.	Handling recalls and withdrawals of prescription drugs?	☐ Yes ☐ No
c.	Making sure that wholesale drug distributors prepare for, protect against, and handle, any crisis that affects security or operation of any facility in the event of strike, fire, flood, other natural disaster, or other emergency situations?	☐ Yes ☐ No
d.	Ensuring that any outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed?	☐ Yes ☐ No
5.	Do you maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs which include all of the following:	
a.	The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped?	☐ Yes ☐ No
b.	The identity and quantity of the drugs received and distributed or disposed of?	☐ Yes ☐ No
c.	The dates of receipt and distribution or other disposition of the drugs?	☐ Yes ☐ No
6.	Are inventories and records maintained and available for inspection for a period of two years after disposition of the drugs?	☐ Yes ☐ No
7.	Do you maintain a list of officers, directors, managers, and other persons who are in charge of wholesale drug distribution, storage, and handling, that includes a description of their duties and a summary of their qualifications?	☐ Yes ☐ No
8.	Do all employees have sufficient education, training, and experience to perform their assigned functions in a manner that assures that the drug product quality, safety and security is maintained at all times?	☐ Yes ☐ No

CERTIFICATION

I certify that I have been authorized by the applicant to complete this compliance check list, and that the answers and statements given are complete, true and correct.

Signature of Contact Person	Date
Title	Telephone Number

The Department of Community Health will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability or political beliefs. If you need assistance with reading, writing, hearing, etc., under the Americans with Disabilities Act, you may make your needs known to this agency.